K051165

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510(K) SUMMARY

SEP - 7 2006

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	4 May 2005
Device Name:	KLS Martin Sternal Talon
Trade Name:	Sternal Talon
Common Name:	Sternal Closure System
Classification Name and Number:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030)
Regulatory Class:	II
Predicate Devices:	Ethi-Pack Surgical Stainless Steel Suture (K931271) Pioneer Silicoat Sternal Cable (K993286) PectoFix DSF System (K000694) Synthes Sternal Fixation System (K010943) Synthes (USA) Sterile Sternal Fixation System (K050041) Sternal Band (K930015) Lorenz Sternal Closure System (K033740) KLS Martin Sternal Plating System (K032413)

Intended Use:

The KLS-Martin Sternal Talon is intended for use in stabilization and fixation of anterior chest wall fractures including Sternal Fixation subsequent to Sternotomy and Sternal reconstructive procedures.

Device Description:

The KLS-Martin Sternal Talon is a two-piece clamping device with various foot depths and lengths that utilizes a ratcheted locking system. Each piece of the device is placed on opposing sides of the sternum and is designed to interlock providing a stabilized fixation thus allowing for various sternal widths. The device has a three position screw which allows the ratchet to open, close and lock. In an emergency situation, the device can be reopened by turning the screw to the open position. A second emergency re-entry is provided by cut points adjacent to the screw.

The KLS Martin Sternal Talon is manufactured from TI-6AL-4V Titanium Alloy

Technological Characteristics:

Similarities to Predicate:

The KLS-Martin Sternal Talon is similar in intended use and indications for use as the Ethi-Pack Surgical Stainless Steel Suture (K931271), Pioneer Silicoat Sternal Cable (K993286), PectoFix DSF System (K000694), Synthes Sternal Fixation System (K010943), Synthes (USA) Sterile Sternal Fixation System (K050041), Sternal Band (K930015), Lorenz Sternal Closure System (K033740) and KLS Martin Sternal Plating System (K032413)

Differences to Predicate:

The KLS-Martin Sternal Talon is a two-piece interlocking system that does not utilize stainless steel sutures, titanium plates or titanium screws for fixation that are utilized in the Ethi-Pack Surgical Stainless Steel Suture

(K931271), Pioneer Silicoat Sternal Cable (K993286), PectoFix DSF System (K000694), Synthes Sternal Fixation System (K010943), Synthes (USA) Sterile Sternal Fixation System (K050041), Sternal Band (K930015), Lorenz Sternal Closure System (K033740) and KLS Martin Sternal Plating System (K032413). The KLS Martin Sternal Talon uses curved foot plates to apply pressure medially to ensure fixation.

Substantial Equivalence:

The KLS-Martin Sternal Talon is substantially equivalent in intended use and indications for use as the Ethi-Pack Surgical Stainless Steel Suture (K931271), Pioneer Silicoat Sternal Cable (K993286), PectoFix DSF System (K000694), Synthes Sternal Fixation System (K010943), Synthes (USA) Sterile Sternal Fixation System (K050041), Sternal Band (K930015), Lorenz Sternal Closure System (K033740) and KLS Martin Sternal Plating System (K032413)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2006

KLS Martin L.P.
% Ms. Jennifer Damato
Director, Regulatory Affairs and Quality Assurance
11239-1 St. Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K051165
Trade/Device Name: KLS Martin Sternal Talon
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: June 16, 2006
Received: June 20, 2006

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

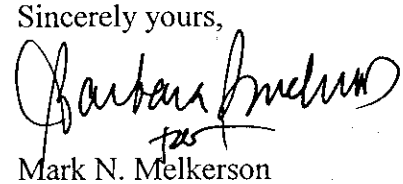
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K051165

510(k) Number (if known):

Device Name: KLS Martin Sternal Talon

Indications For Use:

The KLS-Martin Sternal Talon is intended for use in stabilization and fixation of anterior chest wall fractures including Sternal Fixation subsequent to Sternotomy and Sternal reconstructive procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucknell for MAH

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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